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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/695,499 | 10/28/2003 | Vincenzo Scarlato | 2300-0363.01 | 7930 |

27476 7590 07/17/2007
NOVARTIS VACCINES AND DIAGNOSTICS INC.
CORPORATE INTELLECTUAL PROPERTY R338
P.O. BOX 8097
Emeryville, CA 94662-8097

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| EXAMINER |
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GRASER, JENNIFER E

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| ART UNIT | PAPER NUMBER |
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1645

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| MAIL DATE | DELIVERY MODE |
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07/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/695,499 | SCARLATO ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer E. Graser | 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.--
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 April 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2,3,8,10-13 and 18-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 2 and 3 is/are allowed.

6) Claim(s) 8,10-13 and 18-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 08 October 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. 09/302,626.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 4/16/07.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

1. Acknowledgment and entry of the Amendment submitted on 4/16/07 is made.

Claims 2, 3, 8, 10-13 and 18-21 are currently pending.

Claim Rejections - 35 USC § 112-Scope of Enablement

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8, 10-13 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "an isolated nucleic acid sequence comprising SEQ ID NO:3", 'an isolated nucleic acid sequence which encodes a protein comprising the amino acid sequence set forth in SEQ ID NO:4', and isolated nucleic acid molecules which hybridize to these nucleic acid molecule under high stringency conditions (with the specific conditions recited in claim 13 and the functional limitation that the molecules can detect *N.meningitidis* DNA through hybridization), does not reasonably provide enablement for an isolated nucleic acid which encodes *any* immunogenic polypeptide having 50% or greater identity to an isolated amino acid sequence of SEQ ID NO:4, e.g., variant proteins, an isolated nucleic acid molecule comprising a nucleotide sequence encoding *any* immunogenic polypeptide, wherein the nucleotide sequence has 50% or greater identity to a nucleic acid sequence of SEQ ID No:3 (e.g., variants of SEQ ID NO:3 encoding *any* immunogenic polypeptide), isolated

nucleic acid sequences which encode 10-mer or 25-mer fragments or isolated nucleic acid sequences which encode immunogenic polypeptides which have amino acid sequences which are 80-95% identical to SEQ ID NO:4 without a stated function, e.g., wherein the polypeptide can raise antibodies which specifically bind to SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The breadth of the instant claims is drawn to polynucleotides which are not specified in the sequence disclosure. The specification states that substitutions, additions, or deletions may be made to the defined sequences; however, the specification provides no guidance as to what nucleic acids may be changed without causing a detrimental effect to the adhesion and penetration protein to be produced. Further, it is unpredictable as to which amino acids could be removed and which could be added. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of success are limited. Other positions are critical to the protein's structure/function relationship, e.g., such as various positions or regions directly involved in binding, catalysis in providing the correct three-dimensional spatial orientation of binding and catalytic sites. These regions can tolerate only very little or no substitutions. To start with the DNA sequence first, this requires even more work on the part of the skilled artisan.

The instant claims are drawn to nucleic acids comprising a sequence with a given percent similarity to a nucleic acid which encodes a protein. Selective point mutation to one key residue could eliminate the function of the polypeptide. It could eliminate its function. If the range of decreased binding ability after single point mutation of a protein antigen varies, one could expect point mutations in the protein antigen to cause varying degrees of loss of protection/function, depending on the relative importance to the binding interaction of the altered residue. Alternatively, the combined effects of multiple changes in an antigenic determinant could again result in loss of function. A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies in the polyclonal pool. As stated above, Applicants have not shown which nucleotides may be changed without causing a detrimental effect to the protein in which it encodes. The claims allow for as great as 50% variation. This is a huge variation allowing for many gaps, insertions, substitutions and deletions. It is unclear that a sequence with this much variation would even have the ability to detect *N.meningitidis* in a hybridization assay. Applicants have provided no guidance to enable one of ordinary skill in the art how to determine, without undue experimentation, the effects of different nucleotide substitutions and the nature and extent of the changes that can be made. It is expensive and time consuming to make amino acid substitutions at more than one position, in a particular region of the protein, in view of the many fold possibilities for change in structure and the uncertainty as to what utility will be possessed. See

Mikayama et al. (Nov.1993. Proc.Natl.Acad.Sci. USA, vol. 90 : 10056-10060) which teaches that the three-dimensional structure of molecules is important for their biological function and even a single amino acid difference may account for markedly different biological activities. Rudinger et al. (June 1976. Peptide Hormones. Biol.Council. pages 5-7) also teaches that amino acids owe their 'significance' to their inclusion in a pattern which is directly involved in recognition by, and binding to, the receptor and the significance of the particular amino acids and sequences for different amino acids cannot be predicted *a priori*, but must be determined from case to case by painstaking experimental study. The specification also fails to teach the location of immunogenic epitopes. Therefore, it would take undue experimentation for one of skill in the art to determine which 30 nucleotides would encode a 10-mer immunogenic fragment.

Additionally, the newly amended claims read on variants of SEQ ID NO:3 (50% identity) encoding **any** immunogenic polypeptide, e.g., claim 12: an isolated nucleic acid molecule comprising a nucleotide sequence encoding **any** immunogenic polypeptide, wherein the nucleotide sequence has 50% or greater identity to a nucleic acid sequence of SEQ ID No:3. The claim is not enabled for such scope. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute

enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." Additionally, many of the claims recite fragments or variants of the nucleic acid with no recited function or a function so generic as to not enable one of skill in the art the ability to ascertain the claimed structure and produce it without undue experimentation.

Given the lack of guidance contained in the specification regarding acceptable nucleotide substitutions, additions or deletions, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Response to Applicants' Arguments:

Applicants argue that the claimed compound or composition is limited by a particular use and the claims should be evaluated based upon that limitation.

Applicants argue that the specification on page 45, line 18 through page 46, line 6 discusses use of Neisserial antigens in immunodiagnostic assays for detecting antibody levels and such Neisserial antigens may be expressed using nucleotide sequences as claimed. This argument has been fully and carefully considered, but is **not commensurate in scope with the claimed invention**. The instant claims allow for DNA encoding 'any immunogenic polypeptide with as little as 50% identity to SEQ ID NO:4". These peptides may not have the ability to detect *N.meningitidis*, much less any *Neisseria* bacterium. Further, the claims do not require the polypeptides to have the ability to bind to an amino acid sequence comprising SEQ ID NO:4. Additionally, the

specification fails to provide and enable nucleic acid sequences which could encode such variant sequences. To start with the DNA sequence first, this requires even more work on the part of the skilled artisan. The instant claims recite only a very generic use, e.g., encode an immunogenic polypeptide. This generic scope does not require the polypeptides to specifically bind to an amino acid sequence comprising SEQ ID NO:4 and ultimately detect *N.meningitidis*. Further, it would take a great deal of experimentation on the part of the skilled artisan to begin with the nucleic acid as claimed and work to find acceptable variants which would express the polypeptides having this ability. It is suggested, if written support is provided in the instant claims, that the variants be drawn to sequences which hybridize under specific conditions to SEQ ID NO:3 and can detect *N.meningitidis* DNA.

The instant claims are drawn to variants which differ by 50% from the known sequences. This is a very large amount. It is unclear that sequences differing by this much would have the ability to successfully detect *N.meningitidis*. Additionally, it is unclear how to produce and identify variants which would produce an immunogenic polypeptide with this much variation from the sequences which are taught. This is a huge variation allowing for many gaps, insertions, substitutions and deletions. It is even more unlikely that such variants would produce a functional protein or immunogenic fragment. As stated above, Applicants have provided no guidance to enable one of ordinary skill in the art how to determine, without undue experimentation, the effects of different nucleotide substitutions and the nature and extent of the changes that can be made. It is expensive and time consuming to make amino acid substitutions at more

than one position, in a particular region of the protein, in view of the many fold possibilities for change in structure and the uncertainty as to what utility will be possessed. Further, it would take undue experimentation for one of skill in the art to determine which 30 nucleotides would encode a 10-mer immunogenic fragment, particularly when no immunogenic epitopes have been identified. Given the lack of guidance contained in the specification regarding acceptable nucleotide substitutions, additions or deletions, one of skill in the art could not make or use the broadly claimed invention without undue experimentation. It is suggested that Applicants limit the claims to molecules displaying greater homology, e.g., 90-95% homology, and which are capable of detecting N.meningitidis DNA through hybridization in order to overcome the rejection or wherein the encoded polypeptide can raise antibodies which specifically bind to SEQ ID NO: 4.

Applicants further argue that the cited references, Rudinger and Mikyama, are not relevant since they were published 5 years or many more years prior to the filing of the application. They argue that the claims recite the generic function of immunogenicity and not the biological function of the protein in the bacteria and the cited references have to do with complex biological function and not immunogenicity. This has been fully and carefully considered but is not deemed persuasive. Immunogenicity is a biological function of a protein. The cited references teach, and it is still relevant to date, that selective point mutation to **one** key residue could eliminate the function of the polypeptide. It could eliminate its immunogenicity. If the range of decreased binding ability after single point mutation of a protein antigen varies, one

could expect point mutations in the protein antigen to cause varying degrees of loss of protection/function, depending on the relative importance to the binding interaction of the altered residue. Alternatively, the combined effects of multiple changes in an antigenic determinant could again result in loss of function. A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies in the polyclonal pool. As stated above, Applicants have not shown which nucleotides may be changed without causing a detrimental effect to the protein in which it encodes. The claims allow for as great as 50% variation. This is a huge variation allowing for many gaps, insertions, substitutions and deletions. It is unclear that a sequence with this much variation would even have the ability to detect *N.meningitidis* in a hybridization assay. Applicants have provided no guidance to enable one of ordinary skill in the art how to determine, without undue experimentation, the effects of different nucleotide substitutions and the nature and extent of the changes that can be made. newly amended claims read on variants of SEQ ID NO:3 (50% identity) encoding *any* immunogenic polypeptide, e.g., claim 12: an isolated nucleic acid molecule comprising a nucleotide sequence encoding *any* immunogenic polypeptide, wherein the nucleotide sequence has 50% or greater identity to a nucleic acid sequence of SEQ ID No:3. No teachings or examples can be found for other immunogenic polypeptides, e.g., other than SEQ ID NO: 4 and fragments containing epitopes contained within SEQ ID NO: 4 which have the ability to raise antibodies which recognize the protein.

Claim Rejections - 35 USC § 112-Written Description

4. Claims 8, 10-13 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO: 3 and equivalent degenerative codon sequences thereof and therefore the written description is not commensurate in scope with the claimed invention.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed structure of

the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA..." requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

No disclosure, beyond the mere mention of allelic variants is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only an isolated nucleic acid sequence consisting of SEQ ID NO: 3 and equivalent degenerative codon sequences thereof, but not the full breadth of the claims, meets the written description provisions of 35 USC 112, first paragraph.

Response to Applicant's arguments:

Applicants argue that inapplicable case law was cited. They further argue that a claimed genus may be satisfied through sufficient description of a representative number of species by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Applicants argue on page 10 of their response that they have disclosed twenty one representative species of the claimed genus of an isolated nucleic acid molecule encoding an immunogenic polypeptide having 50% or greater sequence identity to an amino acid sequence of SEQ ID NO: 4. They further argue that software programs could be used to determine polypeptides having antigenicity. They argue that antigenicity is a much lower threshold than a biological function. These arguments have been fully and carefully considered but are not deemed persuasive in overcoming the rejection.

“Antigenicity” is a generic function. The applicant has not identified any common structural core which one skilled in the art could use to identify any genus of polynucleotides. In essence, the applicant is claiming such polynucleotide homologues only by their functionality, that of possessing a generic immunogenicity. More than a statement of biological function is required to satisfy the 112 1st paragraph written

description requirement for a genus of DNA molecules. See e.g. Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 U.S.P.Q.2d 1016, 1027 (CAFC 1991); and Fiers v. Revel, 25 U.S.P.Q.2d 1601, 1604-05 (CAFC 1993). In Amgen v. Chugai, the Court of Appeals for the Federal Circuit stated that "[i]t is not sufficient to define [a DNA] solely by its principal biological property, e.g. encoding of human erythropoietin." Id., at 1021. Rather, "what is necessary is that [the applicant] provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims." Id., at 1027. In these statements, the court has expressly stated that a DNA molecule must be described by means of description other than by naming the encoded protein to satisfy the 112 ¶1 written description requirement. Applicant' claims are even more generic than that involved in the cited case. More recently, the Federal Circuit again took this position. In the case University of California v. Eli Lilly and Co., 43 U.S.P.Q.2d 1398, at 1406 (1997), the court stated that defining a cDNA by its function "is only a definition of a useful result rather than a definition of what achieves that result." The court also stated that such a description "does not define any structural features commonly possessed by members of the genus [of claimed cDNAs] that distinguish them from others." Id. Thus, it is clear that identification of polynucleotide by naming a generic immunogenic fragment it encodes is not sufficient. In the present case, the only description that the applicant has provided for species homologues/variants of SEQ ID NO: 3 is that they must also encode an immunogenic polypeptide. Such a description is clearly insufficient to support the claimed genus. The specification does not provide evidence that one skilled in the art would know what

modifications, and what regions of the coding region to target for modifications, in order to produce a functioning fragment. The generic function recited in the claims does not provide support in determining the claimed structure. Pages 66-65 teach that SEQ ID NO:5 produces a polypeptide having 83.7 % homology to SEQ ID NO: 4 and that SEQ ID NO: 1 produces a polypeptide having 65.7% identity to SEQ ID NO: 4. However, no immunogenicity studies are provided. Merely running sequence alignments is not a constructive reduction to practice.

Former rejections which were previously overcome:

5. Claims 2, 3, 8, 10-13 and 18-21 were formerly rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by Peak, et al (U.S. Patent No. 6,197,312). The Examiner asserted that Peak, et al. has a priority date of December 12, 1997.

Applicants stated that MPEP § 2136.03(II)(c)(1) clearly indicates that a U.S. Patent which claims priority to an international application filed before November 29, 2000 has a critical reference date as of the earlier of the date of completion of 35 U.S.C. 371(c)(1), (2) and (4) or the filing date of the later-filed application that claimed the benefit of the international application. A courtesy copy of the first page of the international application PCT/AU98/01031 to which Peak, et al. appear to claim priority was enclosed (there is a discrepancy in international patent application number on the face of Peak et al. [63] and Col 1, lines 3-5). Since the international application PCT/AU98/01031 was filed before November 29, 2000, the critical date for Peak, et al. is August 9, 1999 (a courtesy copy of the face of Peak, et al. with the filing date highlighted was been provided). Since the priority date of the present application is well

before August 9, 1999, e.g., at least as early as 1/14/98, Peak, et al. does not qualify as 102(e) prior art. See face of Peak et al 6,197,312.

Allowable Subject Matter

6. Claims 2 and 3 are allowed.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

J. Graser
Jennifer Graser 6/9/07
Primary Examiner
Art Unit 1645